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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,982	02/02/2006	Ruggero Fariello	373987-011US (102895)	6583

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
03/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

napatentdept@dechert.com

Office Action Summary	Application No.	Applicant(s)	
	10/559,982	FARIELLO ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-68* is/are pending in the application.

4a) Of the above claim(s) *68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2009 has been entered.

Claim(s) 57-68 are pending. Claim(s) 1-56 are cancelled. Claim(s) 68 is withdrawn from further examination as it is drawn to a non-elected invention. Claim(s) 57-67 are examined herein.

Response to Arguments

Applicant's arguments with respect to the 103(a) rejection of claims 57-64 and 67 as being unpatentable over Dostert (US Patent No. 5,236,957) of record and Birkmayer (US Patent No. 3,795,739) in view of Chazot (Current Opinion in Investigational Drugs, 2001) of record has been fully considered.

Applicant's arguments with respect to the 103(a) rejection of claims 65 and 66 as being unpatentable over Dostert (US Patent No. 5,236,957) and Birkmayer (US Patent No. 3,795,739) in view of Chazot (Current Opinion in Investigational Drugs, 2001) of

record as applied to claims 57-64 and 67 above in view of Chenard (US Patent No. 6,258,827 B1) has been fully considered.

The Declaration of Dr. C. Warren Olanow submitted on November 13, 2009 has been fully considered.

Applicant argues that "the required expectation of success cannot be found in Birkmayer, a patent that long preceded the invention of safinamide and its congeners, nor in Chenard, which is silent with respect to safinamide, its salts, and congeners thereof. Neither is it reasonably to be found in Dostert. Although Dostert describes the use of safinamide and congeners in the treatment of Parkinson's disease - and in a divisional, U.S. Patent No. 5,502,079 (of record), Dostert indeed claims the use of these compounds in methods of treating Parkinson's disease - the Dostert disclosure is completely silent with respect to the subject matter here claimed, the treatment of Parkinson's disease by administration of safinamide as an adjunct to therapeutically effective doses of L-DOPA".

In response to this argument, Examiner respectfully notes that Applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). Furthermore, Examiner is aware that the Dostert reference is silent on the combination with safinamide. For this reason, a secondary reference was brought in on order to show the combination of L-DOPA for treatment of the same condition.

Upon further consideration, the arguments with respect to the Birkmayer reference are persuasive and therefore the rejections of record from the previous Office action are hereby withdrawn. The following new rejections are set forth in the Office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57-64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dostert (US Patent No. 5,236,957) of record and Chiesi (US Patent No. 5,017,607).

Dostert teaches N-phenylalkyl substituted α-amino carboxamide derivatives of formula I as therapeutic agents for the treatment of Parkinson's disease (column 1, line 32-column 2, line 7). Specifically, Dostert teaches (S)-2-[4-(3-fluorobenzyloxy)benzyl]aminopropionamide (column 15, lines 3-4) (a.k.a safinamide).

Dostert additionally teaches pharmaceutically acceptable salts thereof of including among others, methanesulfonic acid (column 2, 28).

Dostert teaches that the compounds may be administered orally at doses ranging from about 50 to about 1500 mg/day (column 12, lines 7-10).

Dostert does not teach the coadministration of L-Dopa which is administered in an amount that alone has therapeutic effect.

Chiesi teaches a method of treating Parkinson's disease containing as the active principle levodopa methyl ester optionally combined with other active principles selected from dopaminergic, anticholinergic, antidepressive drugs, carboxylase and monoaminoxidase inhibitors. In order to improve the therapeutic action, LDME may also be advantageously used in combination with other active principles, selected from peripheral decarboxylase inhibitors, such as carbidopa or benserazide, or selective MAO-B inhibitors, such as Deprenyl (column 3, lines 4-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined safinamide, used to treat Parkinson's disease, as taught by Dostert, with a combination of L-dopa methyl ester and a peripheral decarboxylase inhibitor, as taught by Chiesi, for the same purpose. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Thus, in view of the foregoing art made of record, it would have been obvious to one in the art to have combined L-dopa (with or without decarboxylase inhibitor) with safinamide in the treatment of Parkinson's disease.

Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dostert (US Patent No. 5,236,957) and Chiesi (US Patent No. 5,017,607) as applied to claims 57-64 and 67 above in further view of Chenard (US Patent No. 6,258,827 B1).

Dostert and Chiesi are discussed above.

Neither Dostert nor Chiesi teach the composition further comprising a catechol-*O*-methyltransferase inhibitor, such as tolcapone or entacapone.

Chenard teaches that there are classes of compounds reported as being useful in the treatment of Parkinson's disease namely, among others, D1, D2 agonists, monoamine oxidase-B inhibitors, levodopa and COMT inhibitors (column 12, lines 31-45), wherein COMT inhibitors include tolcapone and entacapone (column 13, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the combination of safinamide and levodopa for the treatment of Parkinson's as taught by Dostert and Chiesi and also administered additional Parkinson's disease agents such as tolcapone or entacapone as taught by Chenard. Because such agents are well known in the art to treat the same disease, it would have been obvious to one in the art to have combined them. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Claims 57-67 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627